IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH

C.R. BARD, INC., *et al.*, Plaintiffs, v. MEDICAL COMPONENTS, INC., Defendant.	**MEMORANDUM DECISION AND ORDER CONSTRUING DISPUTED CLAIM TERMS AND PHRASES** Case No. 2:17-cv-00754 Howard C. Nielson, Jr. United States District Judge

I.

The plaintiffs in this action are C.R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc. (collectively "Bard"). After filing this lawsuit, the Bard plaintiffs became wholly owned subsidiaries of Becton Dickinson & Company. The defendant and counterclaimant is Medical Components, Inc. ("MedComp").

There are six patents involved in this litigation, five asserted by Bard and one by MedComp. The Bard patents are U.S. Patent Nos. 8,025,639 ("the '639 patent"), 8,382,723 ("the '723 patent"), 8,585,663 ("the '663 patent"), 8,603,052 ("the '052 patent") and 9,682,186 ("the '186 patent"). The MedComp patent is U.S. Patent No. 8,852,160 ("the '160 patent").

The Bard '723, '663, '052, and '186 patents named three Bard Access System engineers, Kelly Powers, Jason Stats, and Eddie Burnside, as co-inventors. They are "related" and claim priority to the same ultimate parent application, filed on March 6, 2006, which in turn claims priority to a provisional application filed on March 4, 2005. As a result, although the claims differ, the specifications of the '723, '663, '052, and '186 patents are substantially identical. The Bard '639 patent names five Bard Access System engineers, Kelly Powers, Guy Rome, John

Evans, Dwight Hibdon, and David Cise, as co-inventors. The '639 patent is unrelated to the four other asserted Bard patents and claims priority to an application filed on April 25, 2006. The MedComp '160 patent names four co-inventors, Timothy Schweikert, Raymond Bizup, Kevin Sanford, and Kenneth Zinn, and claims priority to a provisional patent application filed on June 20, 2007.

The five asserted Bard patents and one asserted MedComp patent all relate to the same general technology, vascular access ports, which are implantable medical devices used to deliver medicines or other fluids to a patient. For example, cancer patients frequently receive chemotherapy treatments through an access port. *See* Dkt. No. 405 at 6. As described by the patents-in-suit, a port has a reservoir, a septum that can be pierced by a special needle (called a "cannula" in the patents), and an outlet stem that is attached to tubing (called a "catheter"), which is then inserted into a patient's artery or vein. *See e.g.*, Joint Appendix ("JA"), JA-40 at 2:34–62. Figure 1 of the '639 patent shows the basic components of a port, including the base, the cap, the septum, the reservoir, and the outlet stem that connects to a catheter (not shown):

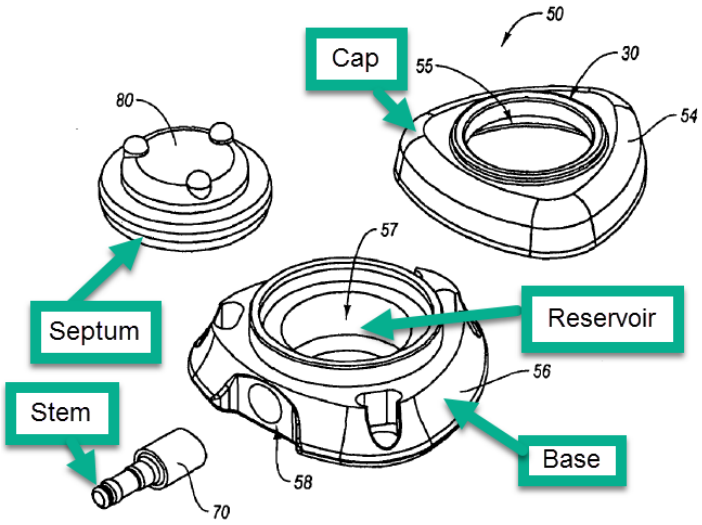
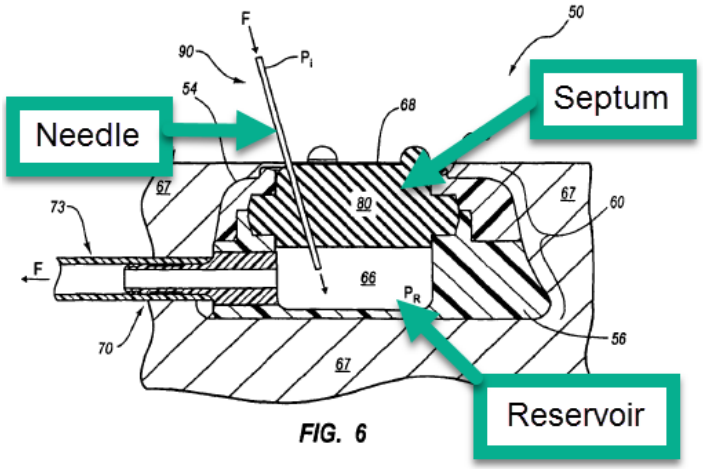


FIG. 1

JA-8 at Fig. 1 (annotations added); *see also* JA-41 at 4:60–61.

Vascular access ports are designed to be implanted beneath the skin, typically in a patient's chest or arm. *See* JA-40 at 2:34–62. Once implanted, the port can be accessed by inserting a needle through the patient's skin and the septum of the port, thereby giving the needle access to the port's reservoir. *See id.* at 2:51–58. Medications can then be injected into the reservoir and ultimately into the patient through the catheter. *See id.* at 2:51–59. Figure 6 of the '639 patent depicts an implanted port being accessed with a needle:



JA-10 at Fig. 6 (annotations added); *see also* JA-42 at 5:3–5. Typically, the needle used to access a port is attached to a short piece of tubing and catheter, which is collectively called an infusion set. *See* JA-48 at 18:28–39.

Vascular access ports were well known by the time each of the asserted patents were filed. *See* JA-40 at 2:34–62. Each of the six patents-in-suit relates to ports used for power injection. *See* JA-41 at 4:4–9; JA-96 at 2:14–21; JA-144 at 2:14–21; JA-192 at 2:14–21; JA-245 at 2:24–31; JA-266 at 1:64–2:9. Power injection typically is used in connection with computed tomography ("CT") scans, which are a special form of X-ray where the X-ray source is controlled by computer. *See* JA-40 at 1:16–60. In order to obtain proper images in a CT scan, contrast media must be injected into a patient above a minimum flow rate. *See id.* at 2:13–34. Because the contrast media is very viscous and the desired flowed rates are relatively high, hand

injections are ineffective for delivering the contrast media into a patient. A power injection machine is accordingly used to deliver the contrast media using mechanical assistance. *See e.g.*, JA-97 at 3:45–61. A power injection procedure generates high pressures within the cavity of the port, within the needle, and within the tubing used to deliver the contrast media into the port. *See* JA-40 at 2:13–34. If a port or infusion set is not capable of withstanding such pressure, power injection can cause leakage or septum rupture in the port or leakage from or bursting of the infusion set. Any of these outcomes could seriously injure the patient.

Bard's asserted '639 patent is directed to a method of power injecting through a port and an infusion set that have been specially adapted to accommodate the flow rates and pressures associated with power injection procedures. *See* JA-41 at 3:29–54. The '639 patent teaches the pressures that a port and infusion set must be able to withstand in order to be suitable for power injection, and it discloses materials and design features that can be implemented to accommodate these requirements. *See* JA-43 at 7:15–8:8.

The remaining Bard asserted patents, the '723, '663, '052, and '186 patents (collectively the "Port ID patents"), address the problem of identifying a port as being suitable for power injection after it has been implanted in a patient. *See e.g.*, JA-96 at 1:58–2:21. Identification is important because power injecting into a port that is not suited for power injection may result in leakage or septum rupture, as discussed. And because ports are placed under the skin, they are not visible after implantation. The '723, '663, '052, and '186 patents claim "power injectable access ports," or port "systems" and "assemblies," that include identifiers that can be used, after a port has been implanted under the skin, to determine that the port is suitable for power injection. *See* JA-101–02; JA-149–50; JA-197–98; JA-251–52. One specific set of identifiers described and claimed in these patents are radiopaque markings viewable by X-ray. *See* JA-97 at

4:10–12, 4:22–26; JA-145 at 4:10–12, 4:22–23; JA-193 at 4:10–12, 4:22–23; JA-246 at 4:20–23, 4:33–34. Because these markings are visible by X-ray, a healthcare professional can observe them after implantation and confirm that a port is suitable for power injection. *See id*. In addition to the radiopaque identifier, the '723, '663, '052, and '186 patents also disclose using unique and identifiable port geometry, such as concave sides, to identify ports as being suitable for power injection. *See* JA-100 at 9:38–50; JA-148 at 9:38–50; JA-196 at 9:38–50; JA-249 at 9:58–10:3.

MedComp's '160 patent is directed to the same general subject matter as the '723, '663, '052, and '186 patents. Like the Bard patents, it teaches the use of a radiopaque identifier to identify a port as power injectable. *See* JA-268 at 5:4–13. The '160 patent requires that the radiopaque marker be a void located on the "base flange . . . of the housing base." JA-267 at 4:56–58.

II.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtr'n Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction is the process by which the meaning and scope of asserted claims is determined and that task "falls 'exclusively within the province of the court,' not that of the jury." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015) (quoting *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 372 (1996)).

There are two sources of evidence courts use to construe patent claims, evidence "intrinsic" to the patent and evidence "extrinsic" to the patent. The "intrinsic record" consists of the patent itself, including the claims and the specification, as well as the prosecution history. *Phillips*, 415 F.3d at 1317. Extrinsic evidence "consists of all evidence external to the patent and

prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id*. When construing a claim term, courts "look first to the language of the claims, followed by the language of the specification and prosecution history." *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1374 (Fed. Cir. 2019). Although extrinsic evidence can be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks omitted).

Ultimately "there is no magic formula or catechism for conducting claim construction." *Id.* at 1324. The court reviews the available sources to determine "what the inventors actually invented and intended to envelop with the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id*.; *accord Phillips*, 415 F.3d at 1316.

A.

The claims, which appear as numbered paragraphs at the end of the patent, "define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312. Courts thus first "look to the words of the claims themselves . . . to define the scope of the patented invention." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *accord SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1304 (Fed. Cir. 2019).

As the Federal Circuit has explained, "the words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp.*, 90 F.3d at 1582). Ordinary and customary meaning is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. "In some cases, the ordinary meaning of claim

language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1313–14.

"Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citations omitted). For each of the patents-in-suit, all of which relate to vascular access ports, the court concludes that a person of ordinary skill in the art would have multiple years of experience (educational or professional) in designing or developing medical devices.

Furthermore, "[p]roper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation." *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999). "Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment" because "claim terms are normally used consistently throughout the patent." *Phillips*, 415 F.3d at 1314.

B.

The specification is a written description of the invention that precedes the claims. The patent "specification is always highly relevant to the claim construction analysis." *Vitronics Corp.*, 90 F.3d at 1582. For example, the patent specification "may reveal a special definition given to a claim term by the patentee that differs from the meaning it may otherwise possess." *Phillips*, 415 F.3d at 1316. But although "the specification can supply understanding of unclear terms," it "should never trump the clear meaning of the claim terms." *Comark Commun., Inc. v.*

Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (citing *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988)). The Federal Circuit has likewise "repeatedly warned" of "the danger of reading limitations from the specification into the claim," *Phillips*, 415 F.3d at 1323, including confining claims to particular embodiments described in the specification, *see id.*, or importing functional limitations "not recited in the claim itself," *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001); *see also E.I. du Pont.*, 849 F.2d at 1433 (holding that it is improper to import an extraneous limitation from the specification into a claim); *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1433 (Fed. Cir. 2000).

C.

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. During prosecution of a patent, a record is created of the back and forth between the Patent and Trademark Office ("Patent Office" or "PTO") and the applicant. That record is called the prosecution history. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

"[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation," however, "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Courts accordingly "indulge a 'heavy presumption' that claim terms carry their full ordinary and customary meaning." *Omega Eng'g Inc, v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). This

heavy presumption carries the day "unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." *Id*. Thus, any disavowal of claim scope made during patent prosecution "must be both clear and unmistakable." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1325 (Fed. Cir. 2013).

D.

"In some cases . . . the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharms.*, 574 U.S. at 331. "Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology," they "have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips*, 415 F.3d at 1318. Expert testimony can also "ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.*

III.

The disputed claim terms and phrases in this action fall into two categories: those that appear in MedComp's asserted patent and those that appear in Bard's asserted patents. The first category comprises four disputed claim terms or phrases: (1) "adjacent"; (2) "housing"; (3) "housing comprising: a base . . .; and a flange"; and (4) "reservoir." The second category comprises five disputed claim terms or phrases: (1) "substantially free of plasticizer"; (2) "body

defining a cavity"; (3) "power injectable access port"; (4) "concave portion"; and (5) "identifier" and "message."

A.

The court first addresses the disputed terms and phrases contained in the MedComp patent. The court adopts the following construction of these terms and phrases:

Term/Phrase	**Court's Construction**	**Bard's Construction**	**MedComp's Construction**
"adjacent"	Nearby, next to, close to, proximate to, or adjoining (taking into account the relative size of the components of a vascular access port).	Next to, adjoining.	No construction necessary. If the court deems construction necessary: nearby, next to, close to, proximate to, or adjoining.
"housing"	The body of the port.	A case or enclosure to cover and protect a structure or a mechanical device.	No construction necessary. If the court deems construction necessary: the body of the port.
"housing comprising: a base . . .; and a flange"	The body of the port includes without limitation a base and a flange.	The housing must contain at least a base and a flange.	No construction necessary. If the court deems construction necessary: the body of the port includes without limitation a base and a flange.
"reservoir"	The cavity or chamber within the port body defined by the base of the port body and beneath the septum.	The portion of the port that holds liquid.	No construction necessary. If the court deems construction necessary: the cavity or chamber within the port body defined by the base of the port body.

1) "adjacent"

The claim term "adjacent" appears in asserted independent claims 1, 9 and 16 of MedComp's '160 patent. *See* JA-268 at 5:24, 5:54, 6:29. Bard's proposed construction is "next to, adjoining." While it is MedComp's position that the term is commonly understood and requires no construction, its proposed construction is "nearby, next to, close to, proximate to, or adjoining."

The court finds that construction is necessary for this term, because there is a clear difference between "next to, adjoining" and "proximate to, close to," and the parties "raise an actual dispute regarding the proper scope of these claims." *O2 Micro International Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). "[T]he court, not the jury, must resolve that dispute." *Id.*; *see also Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1319–20 (Fed. Cir. 2016).

The court adopts MedComp's proposed construction with the added clarification "(taking into account the relative size of components of a vascular access port)." Common English terms should be construed by applying their "ordinary and customary meaning." *Phillips*, 415 F.3d at 1312. Patent case law generally confirms the well-accepted meaning of "adjacent" as not limited to "next to" and "adjoining," but also including "nearby," "close to" and "proximate to." *See, e.g.*, *Maytag Corp. v. Whirlpool Corp.*, 88 F. Supp. 2d 894, 903 (N.D. Ill. 2000) (finding "adjacent" means "'near' or 'close'" and noting "an intervening design element does not prevent two other elements from being 'adjacent' to one another"); *Centennial Molding, LLC v. Carlson*,

401 F. Supp. 2d 985, 991 (D. Neb. 2005) (concluding "adjacent" means "close to; lying near; near or close to but not necessarily touching").[1]

Nothing in the '160 patent specification suggests that the term "adjacent" was assigned a special definition that differs from its ordinary and customary meaning. The term appears only once in the specification. While it is used in the claim to describe the relationship between the flange and the reservoir, it is used in the specification to describe the relationship between a discharge port and a recess. *Compare* JA-267 at 4:6 (specification), *with* JA-268 at 5:24 (claim). Regardless, there is no evidence in the specification that the term is used in any way that differs from its well-accepted meaning. To the contrary, Figure 8 of the '160 patent shows that the discharge port (16) is nearby, next to, or close to the recess (56). *See* JA-263.

The court is also unpersuaded by Bard's argument that the well-accepted meaning of "adjacent" should be limited so that the term means only "next to, adjoining" based on the embodiments depicted in the specification. For example, Bard attempts to show that in Figure 4, the "flange" is next to the "reservoir" by marking up the figure with its own identification of the "flange" and the "reservoir." Dkt. No. 405 at 15. But the specification describes Figures 3 to 7, including Figure 4, as having a "[h]ousing base 28 [that] includes a base flange 36 extending radially outwardly from the bottom of well 30." JA-267 at 3:40–41; *see also* JA-261–62. Bard ignores the fact that the claims, which recite "flange" and not "base flange," are broader than

[1] Bard relies heavily on *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) to justify limiting "adjacent" to "next to" and "adjoining." Although the Federal Circuit construed the term to mean "next to" in that case, however, it actually broadened the meaning adopted by the district court—"contiguous or connected"—finding that construction to be overly limiting and to improperly exclude alternative embodiments. In all events, the specification of the patent at issue in *MBO Labs* described the claimed safety needle element as not just "adjacent" but "*immediately* adjacent" to "the forward surface of the body." U.S. Patent No. RE 36,885 (emphasis added).

such embodiments, and its argument contravenes canons of claim construction by reading limitations into the claims from the specification and confining those claims to particular embodiments described in the specification. *See Phillips*, 415 F.3d at 1323.

Bard's argument also disregards the differentiation between the broader independent claims (1, 9 and 16)—which recite "a flange adjacent to the . . . reservoir"—and narrower dependent claims, which variously recite that "the flange extends outwardly from the . . . reservoir" (claims 3 and 11), "from the well" (claim 18), or "from the base" (claims 4, 12 and 19). JA-268. Figure 4, which depicts "a base flange 36 extending radially outwardly from the bottom of well 30," JA-267 at 3:40–44, is fully consistent with the narrower language of the dependent claims. There is no basis for interpreting this Figure to assign a special meaning to the broader language of the independent claims.

The ordinary and customary meaning of "adjacent" is strongly supported by extrinsic evidence, such as dictionary definitions, as well. *See Phillips*, 415 F.3d at 1318 (recognizing that dictionaries "can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention"). Black's Law Dictionary, for example, defines "adjacent" to mean "[l]ying near or close to, but not necessarily touching. Cf. adjoining." *Adjacent*, Black's Law Dictionary (11th ed. 2019). This is consistent with the definitions offered by other dictionaries as well. *See, e.g.*, *Adjacent*, Oxford English Dictionary (2d ed. 1989) ("lying near or close (to); adjoining; contiguous, bordering. (Not necessarily touching, but this is by no means precluded.)"); *Adjacent*, Webster's Third New International Dictionary (1961) ("to lie near, border on," "not distant or far off," "nearby but not touching"). These dictionaries likewise make clear that the word derives from the Latin verb "adiacere" which means "to lie near." *E.g.*, *id*.

The court thus concludes that the term "adjacent," as used in the independent claims (1, 9, 16)—all of which recite a "flange adjacent to the at least one reservoir," JA-268—does not require the flange to be in contact with the reservoir. The court recognizes that the word "adjacent" does impose some reasonable limits on how far the flange may be from the reservoir, however. But the court will not attempt to articulate a hard limit because the intrinsic patent record does not. It is enough to apply the term's well-accepted meaning and clarify that such meaning must be understood in the context of the patented subject matter, taking into consideration the relative size of the components. The court's construction of "adjacent" is accordingly "nearby, next to, close to, proximate to, or adjoining (taking into account the relative size of the components of a vascular access port)."

2) "housing"

The term "housing" appears in the '160 patent in claims 1, 5, 9, and 16. *See* JA-268. Bard's proposed construction for "housing" is a "case or enclosure to cover and protect a structure or a mechanical device." While it is MedComp's position that the term is commonly understood and requires no construction, its proposed construction is "the body of the port." Because the parties raise an "actual dispute regarding the proper scope of these claims," *O2 Micro International*, 521 F.3d at 1360, the court again rejects MedComp's argument that no construction is necessary, but it adopts MedComp's proposed construction.

One need look no further than the claims themselves to appreciate that "housing" is not properly understood here to mean a "case or enclosure to cover and protect a structure or a mechanical device." The term "housing" is used in the claims as part of the phrase "housing comprising: a base defining at least one reservoir; and a flange adjacent to the at least one

reservoir," JA-268 at 5:23–25, which makes clear that the "housing" at a minimum includes a base and a flange. As used in this phrase, it is clear that the "housing" is "the body of the port."

This meaning is consistent with the patent specification, which describes "housing" to "include a housing base 28 of needle-impenetrable material that includes a well 30 having a bottom floor 32 and side walls 34 that define the interior reservoir" and states that "[h]ousing base 28 includes a base flange." JA-267 at 3:35–40. Bard argues that Figure 1 in the specification shows the "housing" encasing or enclosing the port and that the specification describing the housing base as "needle-impenetrable" demonstrates that it covers and protects the port. *See* Dkt. No. 405 at 17–18. But nothing in the claim language, this Figure, or anything else in the specification suggests that the "housing" is distinct from the port, as is implicit in Bard's proposed construction. To the contrary, it appears that the housing—including the base and the flange—is part of the port.

Nor does anything in the specification state that the function of the "housing" is to "enclose, cover, and protect the port." *See* JA-267–68. Even if such functions could somehow be inferred from the specification, moreover, Bard's proposed construction would improperly import a functional limitation into the claim language. *See Ecolab*, 264 F.3d at 1367 ("Where the function is not recited in the claim itself by the patentee, we do not import such a limitation."); *Senju Pharm. Co. v. Lupin Ltd.*, 780 F.3d 1337, 1346 (Fed. Cir. 2015) ("In composition claims 12–16 of the '045 patent, there is no limitation denoting the function of the composition and we decline to import this limitation into the claims."); *Phillips*, 415 F.3d at 1323; *IMS Tech.*, 206 F.3d at 1433.

The court's construction of "housing" is thus "the body of the port."

3) "a housing comprising: a base . . . and a flange . . ."

The disputed phrase "housing comprising: a base . . .; and a flange" appears in claims 1, 9 and 16 of the '160 patent *See* JA-268. Bard's proposed construction is "the housing must contain at least a base and a flange." While MedComp's maintains that no construction is required, its proposed construction is "the body of the port includes without limitation a base and a flange."

This phrase needs very little construction—the parties dispute only the construction of the term "housing" as used in the patent. The transitional term "comprising" in patent claims is synonymous with "including" and is inclusive or open-ended and does not exclude additional unrecited elements. *See, e.g.*, *Mars, Inc. v. H.J. Heinz Co. L.P.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004). But because the parties raise an "actual dispute" regarding the term "housing," the court must construe this phrase as well. *O2 Micro International*, 521 F.3d at 1360. Given the court's construction of the term "housing," the court adopts MedComp's proposed construction: "the body of the port includes without limitation a base and a flange."

4) "reservoir"

The term "reservoir" appears in claims 1, 3, 4, 9, 11, 12, 16, and 19 of the '160 patent. *See* JA-268. For example, Claim 1 recites, in part, "a base defining at least one reservoir." *Id.* at 5:23–24.

Bard's proposed construction is "the portion of the port that holds liquid." Dkt. No. 405 at 19. According to Bard, the "reservoir is the portion of the port that holds the fluid that then is transferred through the catheter into the body of the patient." *Id*. Bard argues that its proposed construction is "consistent with the plain English meaning of [the] term and how the reservoir is discussed and depicted by the '160 patent." *Id.* Bard adopts its construction from a dictionary definition providing that a "reservoir" is "a place where something is kept in store; as . . . a part

of an apparatus in which a liquid is held." Dkt. No. 405-7 at 4. Bard contends that the '160 patent uses the term "reservoir" consistent with this definition "by repeatedly stating that the 'reservoir' is in 'fluid communication' with the discharge port and catheter to permit infusion and/or withdrawal of fluids from the patient." Dkt. No. 405 at 20. Bard also cites to the figures of the '160 patent, which Bard contends "identify the 'interior reservoir 22' as the void in the middle of the port that holds fluids." *Id.*

MedComp contends that the "term 'reservoir' is readily understandable to the jury and, as such, requires no construction." Dkt. No. 441 at 14. If the term is to be construed, however, MedComp suggests that the term "be described by its structure consistent with the patent's intrinsic record—namely, as 'the cavity or chamber within the port body defined by the base of the port body.'" Dkt. No. 401 at 27. MedComp argues that its proposed construction "trumps Bard's proposal because it provides structural meaning." Dkt. No. 441 at 14. MedComp also notes that "empty space is properly described by what defines it." *Id*. Finally, MedComp argues that Bard's proposed construction would confuse the jury because there are "other elements of the port that can hold liquid." Dkt. No. 401 at 26–27.

Bard argues that construction is necessary because there is an actual dispute between the parties that cannot be left to the jury. *See* Dkt. No. 494 at 95:7–12. Bard disagrees with MedComp's alternate proposed construction because the port septum would be part of, or included within, the reservoir under MedComp's construction. *See id.* at 95:13–21. The claims, however, identify the septum as a separate element, and the specification explicitly describes the reservoir as "beneath" the septum. Dkt. No. 405 at 21 (quoting JA-267 at 3:35–38). Bard explains that the '160 patent teaches that the reservoir is defined by both the port body and the septum—it is the void within the body underneath the septum. *See id*. at 20.

The court rejects Bard's construction that "reservoir" is "the portion of the port that holds liquid." Nowhere in the claims or in the specification is the word "liquid" used to describe the claimed port structure. To define the reservoir port structure solely by its unclaimed capability to hold liquid not only violates the canon of claim construction against reading functional limitations into purely structural claim elements, *see Ecolab*, 264 F.3d at 1367, but also risks confusion with other elements of the port that can hold liquid, which include the "discharge port 16," the "passageway 20," and the "distal tip opening." *See* JA-261 at Fig. 1, 4; JA-267 at 3:24–25. Catheters, infusion sets, and other tubing also can hold liquid. To the extent Bard invokes a dictionary definition in support of its proposed construction, *see* Dkt. No. 405-7 at 4, the court concludes that it employs extrinsic evidence not "to assist in defining a claim limitation" but rather "to limit claim scope based on the purpose of the invention, which is impermissible." *Storage Tech. Corp. v. Cisco Sys.*, Inc., 329 F.3d 823, 832 (Fed. Cir. 2003).

The court also rejects MedComp's argument that no construction is necessary. There does not appear to be any dispute that the reservoir is a void or cavity in the port that holds liquid, and that the sides and bottom of the reservoir are defined by the base of the port. *See* Dkt. No. 494 at 94:21–95:3; Dkt. No. 401 at 26–27; Dkt No. 441 at 14. The parties dispute whether the septum forms the top boundary of the reservoir such that the reservoir is beneath the septum or whether the septum is in the reservoir, however. Because the parties have raised a genuine dispute as to the proper construction of "reservoir," the court must construe the term. *See O2 Micro International*, 521 F.3d at 1360.

While the court rejects Bard's proposed construction, it concludes that MedComp's proposed construction must be modified to make clear that the "reservoir" is separate from and does not include the "septum." As MedComp's counsel admitted at the claim construction

hearing, under MedComp's proposed construction, "the septum is in the reservoir." Dkt. No. 494 at 98:9–10. But this aspect of MedComp's proposed construction is contradicted by both the claims and the specification. First, the claims make clear that the "base," the "septum," and the "reservoir" are all separate and distinct components. *See* JA-268 at 5:23–24, 5:31–32. "Where a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (*quoting Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004)) (alteration in *Becton, Dickinson & Co.*). Second, referencing Figures 3 to 7 in the '160 patent, the specification unambiguously describes the reservoir as "beneath" the septum: "Housing 12 is shown to include a housing base 28 of needle-impenetrable material that includes a well 30 having a bottom floor 32 and side walls 34 that *define the interior reservoir 22 beneath septum 14*." JA-267 at 3:35–38 (emphasis added). Figure 4 in the '160 patent likewise clearly shows the "reservoir" to be beneath the septum:

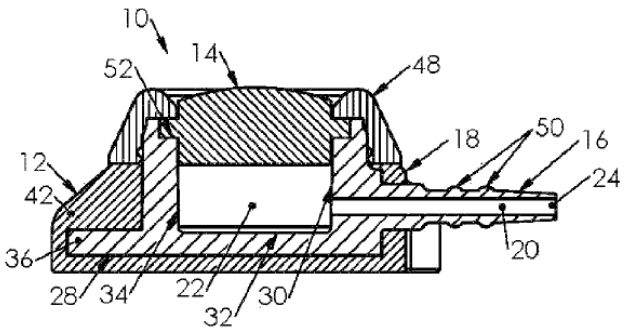


FIG. 4

JA-261.

This figure makes clear that the housing base (28) bounds the reservoir (22) on the sides (34) and bottom (32) while the interior reservoir (22) is clearly beneath the septum (14).[2] *See* JA-261. Nothing in the specification states or suggests that the septum is located within the reservoir. To the contrary, the specification shows that, consistent with MedComp's characterization, the reservoir is "empty space" that is defined by both the walls of the housing base and the septum. *See* Dkt. No. 441 at 14. "When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Sinorgchem Co., Shandong v. Int'l Trade Com'n*, 511 F.3d 1132, 1138 (Fed. Cir. 2007) (*quoting Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Clarifying MedComp's proposed construction to limit the "reservoir" to the cavity that is "beneath the septum" results in "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention." *Renishaw*, 158 F.3d at 1250.

The court accordingly construes "reservoir" to mean to "the cavity or chamber within the port body defined by the base of the port body and beneath the septum."

B.

The court next addresses the disputed terms and phrases contained in the Bard patents. The court adopts the following construction of these terms and phrases:

[2] To be sure, the specification describes an "interior reservoir," but there is no evidence in the claim or specification to suggest that there is any difference between the "interior reservoir" and the "reservoir."

Term/Phrase	Court's Construction	Bard's Construction	MedComp's Construction
"substantially free of plasticizer"	Largely free of an additive to impart flexibility, workability, or stretchability.	Largely free of an additive to impart flexibility, workability, or stretchability.	Does not contain DEHP.
"power injectable access port"	A port that can be injected and pressurized by mechanical assistance (where pressurization by mechanical assistance does not include injection by hand, for example via a syringe including a needle).	A port that can be injected and pressurized by mechanical assistance.	An access port that is capable of being used in a power injection procedure.
"concave portion"	Section or region of a port that is curved inward.	Section or region of a port that is curved inward.	A region of the port surface (distinct from the outlet side region) that is curved into the interior of the port and provided for port identification.
"body defining a cavity"	"Body" means the structural component(s) of the port; "defining a cavity" means marking the boundaries of a cavity.	"Body" means the structural component(s) of the port; "defining a cavity" means marking the boundaries of a cavity.	The component of the port that delineates the cavity.
"identifier/message"	The court finds that the printed matter doctrine is applicable. The claimed terms are not entitled to any patentable weight.	Plain and ordinary meaning (printed matter doctrine is inapplicable).	A feature of the port that is not printed matter.

1) "substantially free of plasticizer"

The phrase "substantially free of plasticizer" appears in claims 1, 11, and 12 of Bard's '639 patent. *See* JA-55 at 31:1, 32:25–26, 32:28. This phrase contains two parts—"substantially free of" and "plasticizer." The parties disagree over the constructions of both parts.

Bard proposes that "plasticizer" be construed to mean "an additive to impart flexibility, workability, or stretchability." Dkt. No. 405 at 21–22. Relying on two dictionary definitions as evidence of the ordinary and customary meaning of "plasticizer," *see* Dkt. Nos. 405-8, 405-9, Bard argues that plasticizers are a "well-known class of additives" used "to impart flexibility and other similar characteristics." Dkt. No. 405 at 22. According to Bard, the specification uses the term "plasticizer" consistent with its ordinary meaning to refer to a class of potential additives, of which DEHP is but one example. *See id.* The specification thus teaches that "any polymer, such as TECOTHANE® type material may be at least substantially free of a plasticizer, *such as, for instance,* Di(2-Ethylhexyl)Phthalate ('DEHP')." JA-49 at 19:3–6 (emphasis added).

MedComp contends that "plasticizer" should be construed to mean "DEHP" because "[t]he only example given for plasticizer in the entire specification is Di (2-Ethylhexyl) Phthalate ('DEHP')" and because, in 2002, the FDA issued draft guidance recommending "that medical device manufacturers consider replacing PVC containing DEHP with alternative materials" and "[f]or devices containing DEHP, . . . that manufacturers 'clearly indicate through user labeling that your device contains DEHP.'" Dkt. No. 401 at 21. Based on this draft guidance, MedComp argues that "the concept of avoiding DEHP in tubing and connectors of an infusion set is not a Bard invention; rather, its genesis is FDA patient safety and labeling requirements." *Id.* MedComp points to internal Bard documents that refer to this draft guidance and notes that no other rationale is provided in the prosecution history for including this limitation. *See id.* at 21–

22. According to MedComp, Bard explained neither "how a material substantially free of plasticizer is relevant to achieving a burst pressure of at least 100 psi for the claimed infusion set tubing and connector" nor, apart from the references to the draft guidance, "why the 'substantially free of plasticizer' limitation was added at all." *Id.* at 23. MedComp maintains that Bard's claim amendment adding this limitation thus sought "patent protection for (and forecloses competitors from following) well-known and patent ineligible FDA guidance." *Id.*

The parties also dispute the meaning of "substantially free of." Bard contends that "substantially" is a term of degree that should be construed to mean "largely." Dkt. No. 405 at 23 (citing *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1368 (Fed. Cir. 2004)). MedComp argues that "substantially free of" should be construed to mean "does not contain." Dkt. No. 401 at 23. Because the draft FDA guidance document "points to the presence of DEHP, not the amount," MedComp argues that "one skilled in the art would understand the motivation to avoid incorporating DEHP and, in so doing, to avoid having to label products as containing the suspected carcinogen." *Id.*

For the following reasons, the court adopts Bard's construction and concludes that "substantially free of plasticizer" means "largely free of an additive to impart flexibility, workability, or stretchability." First, the claim uses the term "plasticizer," not "DEHP." Construing "plasticizer" to mean only "DEHP" would mean that tubing or connectors containing large quantities of plasticizers other than DEHP are "substantially free of plasticizer" so long as they contain no DEHP. This result is extremely difficult to square with the claim language: the inventors could have used the term "DEHP" instead of "plasticizer" if they intended to claim only tubing and connectors "substantially free of DEHP."

As explained, moreover, the specification explicitly identifies DEHP as just one example of a plasticizer. *See* JA-49 at 19:3–6. And "although the specification often describes very specific embodiments of the invention," the Federal Circuit has "repeatedly warned against confining the claims to those embodiments." *Phillips*, 415 F.3d at 1323. The term "plasticizer" should accordingly not be limited to DEHP. The dictionary definitions provided by Bard—which "can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention," *id*. at 1318—also confirm that the ordinary and customary meaning of "plasticizer" encompasses more than just DEHP.

As for the term "substantially," the Federal Circuit has held that "words of approximation, such as 'generally' and 'substantially,' are descriptive terms commonly used in patent claims 'to avoid a strict numerical boundary to the specified parameter.'" *Liquid Dynamics*, 355 F.3d at 1368 (quoting *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1310–11 (Fed. Cir. 2003)). Bard's proposed construction comports with this case law by adding the words "largely free" to its proposed construction. MedComp's proposed construction of "does not contain," by contrast, effectively reads "substantially" out of the claim and requires a strict numerical boundary that is inconsistent with Federal Circuit precedent. Had the inventors intended to claim only tubing and connectors that are entirely free of plasticizers, they could have said "free of plasticizers" instead of "substantially free of plasticizers." (Or, if the intended to claim only tubing and connectors entirely free of DEHP, they could have simply said "free of DEHP.")

The court finds MedComp's arguments regarding the draft FDA guidance document to be unpersuasive. The draft guidance is not cited in the specification or prosecution history. Rather, it is extrinsic evidence that is completely divorced from any disclosure in the specification or file

history and that MedComp is attempting to use to narrow the scope of the claims. The Federal Circuit has rejected this approach to claim construction. *See Storage Tech.*, 329 F.3d at 832 ("Moreover, the district court did not use the extrinsic evidence to assist in defining a claim limitation, but rather used it to limit claim scope based on the purpose of the invention, which is impermissible.").

2) "power injectable access port"

The phrase "power injectable access port" appears in claims 1–5 and 8–10 of the '052 patent, claims 1, 3–7, and 10 of the '663 patent, and claims 1, 7, 8, 12, 14, 16, 21, and 27 of the '186 patent. *See* JA-197–98; JA-149–50; JA-251–52. Bard proposes the following construction: "a port that can be injected and pressurized by mechanical assistance." Dkt. No. 405 at 23. It draws this construction from the specification, which Bard contends defines the contested phrase within the context of the invention. *See id*. (citing JA-97 at 3:43–49); *see also* JA-145 at 3:45–49. MedComp's proposed construction is "an access port that is capable of being used in a power injection procedure." Dkt. No. 441 at 8. MedComp contends that Bard's proposed construction invites confusion because "ports not rated for power injection can also receive mechanically-assisted injection (albeit at low flow rates and pressures)." *Id.* The court adopts a modified version of Bard's proposed construction and construes this phrase to mean "a port that can be injected and pressurized by mechanical assistance (where pressurization by mechanical assistance does not include injection by hand, for example via a syringe including a needle)."

The court agrees with Bard that the specification defines the phrase "power injectable access port." The specification states that an "access port may be injected by hand (e.g., via a syringe including a needle) for example, or may be injected and pressurized by mechanical assistance (e.g., a so-called power injectable port)." JA-145 at 3:45–49. The specification thus

defines a "power injectable port" as a port that "may be injected and pressurized by mechanical assistance," and it distinguishes between injection and pressurization "by mechanical assistance" and injection "by hand," including "via a syringe including a needle." *Id.* The court sees no material difference between a "power injectable port" and a "power injectable access port," and the Federal Circuit has made clear that "a definition set forth in the specification governs the meaning of the claims." *Sinorgchem*, 511 F.3d at 1138. If taken literally, however, the phrase "injected and pressurized by mechanical assistance" could be understood to include hand injections using a syringe and needle because even a syringe provides "mechanical assistance." But it is clear from the specification that this phrase is not intended to include such injections. The court will accordingly construe "power injectable access port" as the phrase is defined in the specification—"a port that can be injected and pressurized by mechanical assistance"—with the additional clarification that "pressurization by mechanical assistance does not include injection by hand, for example via a syringe including a needle."

3) "concave portion"

The phrase "concave portion" appears in claims 1 and 2 of the '723 patent, claims 1 and 2 of the '052 patent, claims 1 and 3 of the '663 patent, and claims 1 and 16 of the '186 patent. *See* JA-101–02 at 12:58, 13:2–3; JA-197–96 at 12:58–61, 13:2–3; JA-149–50 at 12:60–67, 13:10–13; JA-251 at 13:17–26, 14:28–36. Bard proposes that this phrase should be construed as a "section or region of a port that is curved inward." Dkt. No. 405 at 24. MedComp proposes that the phrase should be construed as "a region of the port surface (distinct from the outlet side region) that is curved into the interior of the port and provided for port identification." Dkt. No. 401 at 16. At the claim construction hearing, MedComp agreed with the court that the "distinct from the side region" parenthetical in its construction is unnecessary. *See* Dkt. No. 494 at 125:9–24. The

parties' dispute therefore centers on whether the "concave portion" must be "provided for port identification," as MedComp contends. For the following reasons, the court disagrees with MedComp's attempt to import a functional limitation into the phrase, and adopts Bard's proposed construction.

First, the Federal Circuit has repeatedly cautioned that courts should "avoid the danger of reading limitations from the specification into the claim." *Phillips*, 415 F.3d at 1323; *see also E.I. du Pont*, 849 F.2d at 1433; *IMS Tech.*, 206 F.3d at 1433. Indeed, the Federal Circuit has expressly held that "[w]here the function is not recited in the claim itself by the patentee, we do not import such a limitation." *Ecolab*, 264 F.3d at 1367; *see also Toro Co. v. White Consol. Industries, Inc.*, 266 F.3d 1367, 1371 (Fed. Cir. 2001) ("This court's claim construction, however, did not and could not import into the claim a function from the specification, particularly when the claim recites only purely structural limitations."); *Senju Pharm.*, 780 F.3d at 1346 ("In composition claims 12–16 of the '045 patent, there is no limitation denoting the function of the composition and we decline to import this limitation into the claims.").

To be sure, the Federal Circuit made clear in *Medrad, Inc. v. MRI Devices Corp.* that the rule in *Ecolab* is not absolute. *See* 401 F.3d 1313, 1319 (Fed. Cir. 2005). There the Federal Circuit explained that *Ecolab* "set forth and applied the unremarkable proposition that where a function 'is not recited in the claim itself by the patentee, we do not import such a limitation.' *Ecolab*, 264 F.3d at 1367." *Id.* at 1319. The court rejected the "broad proposition that it is never proper for a court, when construing claim terms, to consider how a claimed device functions." *Id.* The court said this broad proposition was "an overreading of *Ecolab*" and would extend the *Ecolab* principle "to reach a nonsensical result." *Id.* The court then stated that "[i]t is therefore entirely proper to consider the functions of an invention in seeking to determine the meaning of

particular claim language." *Id.*; *cf. Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1178–80 (Fed. Cir. 2008) (holding that the term "smooth" could be defined functionally in light of "evidence from the prosecution history").

There is undeniably some tension between at least some of the court's language in *Medrad* and the rule in *Ecolab*. But the Federal Circuit in *Medrad* did not overrule *Ecolab*, and *Ecolab*'s general rule that a functional limitation should not be imported when it is not recited in the claim itself is still binding precedent. Reconciling the two cases, this court concludes that whether it is appropriate to consider a function set forth in the specification but not mentioned in the claims turns on whether the claim language is itself clear or ambiguous. While it may be appropriate to consider such a function as an aid to interpreting ambiguous language in a claim, the court concludes that it is not appropriate to employ such a function to limit the scope of claim language that is otherwise clear. *Cf. Comark Commun.*, 156 F.3d at 1187 (explaining that although "the specification can supply understanding of unclear terms," it "should never trump the clear meaning of the claim terms").

The court notes that other district courts have reached somewhat similar conclusions. For example, in *American Superconductor Corp. v. S & C Electric Co.*, the court reconciled *Medrad* and *Ecolab* as follows:

> In *Medrad*, the court had very little guidance in the patent for the definition of the term "substantially uniform;" it therefore looked to the preamble and to the "conventional understanding of the term in the NMI industry" and found that "substantial" in that instance meant values close enough to uniformity that were "sufficient" to produce useful images. *Medrad*, 401 F.3d 1313 at 1320. In *Ecolab*, by contrast, there was structural language in the claim, specification, and prosecution history that made the addition of a functional limitation unnecessary to understand the scope of what was covered by the term "substantially uniform." *Ecolab*, 264 F.3d 1358, 1369.

No. 11-10033-FDS, 2012 WL 5932071, at *7 (D. Mass. Nov. 26, 2012); *cf. QXMedical, LLC v. Vascular Sols.*, LLC, No. 17-CV-1969 (PJS/TNL), 2018 WL 5617568, at *5 (D. Minn. Oct. 30, 2018) (noting that the Federal Circuit in *Medrad* "adopted a functional definition" because the claim itself provided little guidance for how to construe the term "substantially uniform").

MedComp, however, argues *Ecolab* should be understood narrowly and that its "general warning against reading functional limitations into purely structural claim elements does not apply where, as here, such functional limitations are explicitly set out in the intrinsic record." Dkt. No. 509 at 14 n.8. But this argument is difficult to square with *Ecolab*'s holding, reaffirmed in *Medrad*, that "[w]here the function is not recited *in the claim itself* by the patentee, we do not import such a limitation." *Ecolab*, 264 F.3d at 1367 (emphasis added). *Ecolab* nowhere articulates an exception to this rule for functional limitations not stated in the claim but supported by the specification. To be sure, MedComp is correct that the court in *Ecolab* "refused to import a limitation into the claim language concerning a homogenous detergent solution" in part because "the patent specification noted the functional importance of having a homogenous *cast*, not a homogenous *detergent solution*." Dkt. No. 509 at 143 n.8 (citing *Ecolab*, 264 F.3d at 1365–69). But after noting that the specification referred to homogenous cast and not homogenous solution, the court in *Ecolab* went on to invoke the general rule against importing functional limitations not stated in a claim as an additional, independent reason supporting its conclusion. *See Ecolab*, 264 F.3d at 1367 ("Furthermore, the fact that the claimed composition was designed to solve certain problems of the prior art and the fact that the patentee noted the functional import of having a homogeneous cast does not mean that we must attribute a function to the nonfunctional phrase 'substantially uniform.'").

In this case, the meaning of the phrase "concave portion" is clear. The ordinary and customary meaning of "concave" to a person of ordinary skill in the art is "curved inward." *See C.R. Bard, Inc. v. AngioDynamics, Inc.*, 748 Fed. Appx. 1009, 1012 (Fed. Cir. 2018) (noting that in the claims of Bard's 7,959,615 patent, "the identifiable feature is one or more 'concave side surfaces' that *curve inward* toward the port housing") (emphasis added). MedComp does not dispute this meaning of "concave" or suggest that this term is ambiguous. Rather, MedComp urges this court to read a "port identification" function into the claim phrase "concave portion" because, it argues, the specification teaches that "'concave portion' is all about port identification," Dkt. No. 441 at 7–8, and that the "sole object of the recited surface shape (no matter how many concave portions it sports) is for port identification." Dkt. No. 401 at 126.

Because the claim language is clear, the court finds that the general rule set forth in *Ecolab* applies here, even if MedComp is correct that the specification establishes that the "sole function" of the "concave portion" is port identification. Like MedComp, *Ecolab* argued at both the district court and the Federal Circuit that the disputed structural claim term—"a three-dimensional, solid, cast, hydrated, substantially uniform alkaline detergent"—included an unclaimed functional element because the specification noted the functional importance of having a "substantially uniform" cast. *Ecolab*, 264 F.3d at 1361, 1365. In rejecting *Ecolab*'s argument, the Federal Circuit recognized that the specification taught the functional importance of the claimed "substantially uniform" cast, and it recognized that, in an amendment during prosecution, the applicant even touted that function as the solution to problems associated with prior art solid detergents. *Id.* at 1367. Yet the court there held that "the fact that the claimed composition was designed to solve certain problems of the prior art and the fact that the patentee noted the functional import of having a homogeneous cast does not mean that we must attribute a

function to the nonfunctional phrase 'substantially uniform.'" *Id.* The court will not adopt here arguments that essentially repeat those considered and rejected by the Federal Circuit in *Ecolab*.

MedComp's arguments regarding the prosecution history are likewise unconvincing. MedComp points to the prosecution history of an earlier patent application in the same family (now U.S. Patent No. 7,959,615 ("the '615 patent")) and argues that because Bard amended the claims in the '615 patent to require a port identification function be performed by a concave side surface, the "concave portion" claim limitation in the patents at issue here must also perform this function. *See* Dkt. No. 494 at 132:8–133:15. MedComp thus invokes the doctrine of prosecution disclaimer, which "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g*, 334 F.3d at 1323.

This doctrine, however, will "attach[] and narrow[] the ordinary meaning of the claim," only in situations "where the patentee has unequivocally disavowed a certain meaning to obtain his patent." *Id.* at 1324. Because courts "indulge a 'heavy presumption' that claim terms carry their full ordinary and customary meaning unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution," *id.* at 1323, "the disavowal must be both clear and unmistakable," *3M Innovative*, 725 F.3d at 1325. If the alleged disavowal "is ambiguous, or even 'amenable to multiple reasonable interpretations,'" the Federal Circuit has declined to find prosecution disclaimer. *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (quoting *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1359 (Fed. Cir. 2003)). "The party seeking to invoke" the doctrine has the "burden of proving the existence of a 'clear and unmistakable'" disavowal. *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1063–64 (Fed. Cir. 2016).

The court finds that MedComp has failed to carry this burden. The '615 patent claims originally required "at least one structural feature of the access port identifying the access port subsequent to subcutaneous implantation as a particular type of access port." JA-1267. After some back and forth with the Patent Office over the patentability of an access port with that limitation, Bard amended its claims to recite:

> at least one structural feature of the access port identifying the access port subsequent to subcutaneous implantation as a particular type of access port, the at least one structural feature comprising a concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

JA-1424. The Patent Office issued the Notice of Allowance thereafter. *See* JA-1439. The prosecution history thus makes clear that Bard amended claims requiring a particular function—port identification—to also require a particular structure, a concave side surface.

If anything, the '615 patent's prosecution history actually supports Bard's argument that it would be improper here to import a functional limitation into the "concave portion" phrase. The '615 patent demonstrates that when Bard wanted to claim a specific function of the "concave portion" or limit the "concave portion" to a specific function, it knew how to do just that. Bard's decision to claim the specific function of the port's concavity in the '615 patent, and its decision to leave that function out of the claims of the patents at issue here, demonstrates that the structural phrase, "concave portion," should not be limited to a specific function. *Cf. Phillips*, 415 F.3d at 1324 ("The other claims of the '798 patent specify particular functions to be served by the baffles. . . . The inclusion of such a specific [functional] limitation . . . in claim 2 makes it likely that the patentee did not contemplate that the term 'baffles' already contained that limitation.").

For the foregoing reasons, the court adopts Bard's proposed construction and interprets "concave portion" to be a "section or region of a port that is curved inward."

4) "body defining a cavity"

The phrase "body defining a cavity" appears in claims 1 and 10 of Bard's '639 patent, claim 1 of Bard's '723 patent, claim 1 of Bard's '052 patent, and claim 1 of Bard's '663 patent. *See* JA-54 at 30:54–55; JA-55 at 32:8–9; JA-101 at 12:54; JA-197 at 12:54; JA-149 at 12:56. Although the '723 patent, the '052 patent, and the '663 patent are all part of the same patent family and share a common specification, the '639 patent is from a separate patent family and has a different specification. *Compare* JA-56; JA-151; JA-103 *with* JA-1.

Bard proposes construing the phrase "body defining a cavity" in two parts—"body" means "the structural component(s) of the port" and "defining a cavity" means "marking the boundaries of a cavity." Dkt. No. 405 at 25. MedComp proposes construing the phrase to mean "the component of the port that delineates the cavity." Dkt. No. 401 at 18. Under Bard's proposed construction, the cavity need not be defined solely by the body of the port and that body is not limited to those components that define the cavity. *See* Dkt. No. 405 at 25. Under MedComp's proposed construction, by contrast, the "cavity is determined by nothing other than the body," and "any component that does not have a role in delineating the boundaries of the cavity cannot be considered part of the 'body.'" Dkt. No. 401 at 20. Because the court finds that Bard's proposed construction is consistent with how the disputed phrase is used in the specifications and at least some of the claims, it adopts Bard's construction.

The court begins its analysis by considering how a person of ordinary skill in the art would read the disputed claim phrase "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. The common specification of the '723, '052, and '663 patents teaches that the "body" is "defined by" both a cap and a base: "Access port 10 includes a housing or

body 20 defined by a cap 14 and a base 16. Cap 14 and base 16, as known in the art, may be configured for capturing there between a septum 18." JA-97 at 4:36–39 (emphasis added); *see also* JA-43 at 7:52–53 (describing the housing or body as defined by a cap and a base). The specification also makes clear that although the "cap 14" is included in the definition of a "body," and therefore must be part of the body, it does not define the boundaries of the cavity, as shown in the annotated version of Figure 1B below.

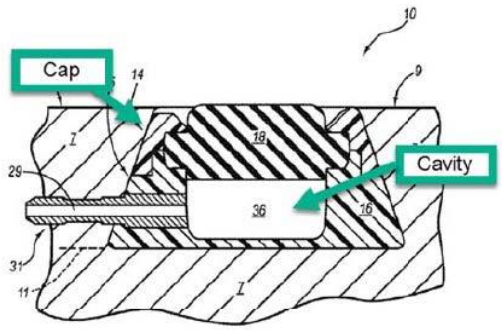


FIG. 1B

Dkt. No. 405 at 26 (citing JA-66 at Fig. 1B) (annotations added). A review of the specification thus establishes that the port "body" is not limited to the specific components that physically delineate the cavity.

At least some of the claims likewise use the term "body" in the same way. Claim 2 of the '663 patent, for example, requires that "the body comprises a cap and a base." JA-150 at 13:6. As discussed, the "cap" does not delineate the cavity. Under MedComp's proposed construction where any component that does not have a role in delineating the boundaries of the cavity cannot be part of the "body," claim 2 of the '663 patent would be internally inconsistent: although the construction of "body" would exclude the cap, claim 2 explicitly requires that the body include

the cap.[3] Because "claim terms are normally used consistently throughout the patent," *Phillips*, 415 F.3d at 1314, the fact that MedComp's proposed construction cannot be reconciled with at least some of the claims of the'723, '052, and '663 patents suggests that it should not be adopted for any of the claims of these patents.

To be sure, the '639 patent is not part of the same patent family as the '723, '052, and '663 patents, and its patent specification does not have the same exact language as the others. Although the relevant language of the '639 patent is somewhat less clear than the other patents, the court nevertheless concludes that it supports the same construction for "body defining a cavity." The summary of the '639 patent, for example, states that "an access port for providing subcutaneous access to a patient may comprise a body including an upper surface and a lower surface and at least one gel region positioned generally between the upper surface and the lower surface." JA-41 at 4:31–34. This description suggests that the body comprises components that do not delineate the cavity such as the upper surface, which is located above the "gel region"—apparently the septum—that presumably defines the top of the cavity. In addition, the patent specification states that "[g]enerally, cap 54 and base 56 may collectively form a housing 60 for capturing septum 80 and at least partially defining reservoir 66." JA-43 at 7:59–61. This language makes clear that the housing may comprise a cap and base but that these components need only "partially" define the reservoir. It likewise suggests that the cap may be located above the septum that presumably defines the top of the reservoir. This language is thus consistent with

[3] Independent claim 1 would also exclude material covered by dependent claim 2 in contravention of one of the canons of claim construction. *See Trustees of Columbia Univ. in City of N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016) (stating that "in a situation where dependent claims have no meaningful difference other than an added limitation," "construing the independent claim to exclude material covered by the dependent claim would be inconsistent").

that of the other three patents, all of which clearly indicate that the cap, though part of the body, does not delineate the cavity.

MedComp nevertheless argues that its narrower proposed construction is warranted based on amendments made during prosecution of applications in both patent families. *See* Dkt. No. 401 at 19–20. According to MedComp, when Bard amended the claims of the parent applications to the '639, '723, '052, and '663 patents, it defined the phrase "body defining a cavity" to exclude portions, like the cap, that do not delineate the cavity. *See id.*

As explained, the doctrine of prosecution disclaimer will "attach[] and narrow[] the ordinary meaning of the claim," only in situations "where the patentee has unequivocally disavowed a certain meaning to obtain his patent." *Omega Eng'g*, 334 F.3d at 1324. That is, "the disavowal must be both clear and unmistakable." *3M Innovative*, 725 F.3d at 1325. If the alleged disavowal "is ambiguous, or even 'amenable to multiple reasonable interpretations,'" the doctrine does not apply. *Avid Tech.*, 812 F.3d at 1045 (quoting *Cordis Corp.*, 339 F.3d at 1359).

With respect to the '723, '052, and '663 patents, MedComp argues that Bard narrowed its claims during prosecution by amending two earlier related patent applications to include the phrase "body defining a cavity." *See* Dkt. No. 509 at 9–10.[4] But the Federal Circuit has repeatedly held that prosecution disclaimer does not apply where the record is silent as to the reason for claim amendment. *See Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002) ("Although prosecution history can be a useful tool for interpreting claim terms, it cannot be used to limit the scope of a claim unless the applicant *took a position* before the PTO.") (emphasis added); *York Prod., Inc. v. Cent. Tractor Farm & Family Ctr.*, 99

[4] MedComp relies on amendments made during prosecution of U.S. Patent Application Nos. 11/368,954 ("the '954 application") and 12/023,280 ("the '280 application"). *See* Dkt No. 509 at 9.

F.3d 1568, 1575 (Fed. Cir. 1996) (holding that, where "the file history does not contain a single statement that the inventors conceded any coverage based on [prior art]," the prosecution history could not limit the claim scope because, "[u]nless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage"); *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1326 (Fed. Cir. 2001) ("Just as we can draw no inference [on the meaning of claim terms] from what the examiner did not say, we can draw no inference from what DeMarini did not argue.").

After analyzing the relevant prosecution histories, the court finds that they are silent as to the reasons for the preliminary amendments on which MedComp relies. *See* JA-432; JA-437; JA-1267; JA-1271. MedComp nevertheless asks the court to infer that the amendments were made to overcome prior art. MedComp argues that the claims as originally submitted "included 'a body' and 'a cavity defined within the body,'" but that "Bard deleted the phrase 'cavity defined within the body' and added 'defining a cavity' to the word 'body'" after "an international prior art search uncovered a reference that teaches a 'cavity defined within a body.'" Dkt. No. 401 at 19. MedComp argues that the phrase "body defining a cavity" must thus "have a different, narrower meaning than the phrase 'cavity defined within the body'" and, as a result, "the body is the sole structural element that establishes all the boundaries of the cavity (this is the same as saying that the cavity is determined by nothing other than the body)." *Id.* at 19–20.

The court rejects this argument. First, there is no evidence in the prosecution history linking the amendments to Bard's submission of the international search report.[5] Second, Bard

[5] The "international prior art search" on which MedComp relies was submitted to the Patent Office as part of an Information Disclosure Statement ("IDS") more than three months before the preliminary amendment was made to both applications. *See* JA-422 (demonstrating that the IDS for the '954 application was submitted on April 1, 2009); JA-1262 (same for the

amended the claim language "a body configured for retaining a septum for repeatedly inserting a needle therethrough into a cavity defined within the body" to "a body defining a cavity accessible by inserting a needle through a septum." JA-432; JA-1267. In both iterations, a needle is inserted through a septum into a cavity, and in both iterations, the body *and the septum* define the boundaries of the cavity. Although Bard's amendment changed the claim language from the passive to the active voice, it did not clearly change the meaning of this language. The court therefore declines to adopt MedComp's proposed inference.

The preliminary amendment thus does not amount to a clear and unmistakable disavowal of Bard's proposed construction of "body defining a cavity." The Federal Circuit has consistently declined to find disavowal under such circumstances, and this court declines to find one here. *See Omega Eng'g*, 334 F.3d at 1324 ("We have, however, declined to apply the doctrine of prosecution disclaimer where the alleged disavowal of claim scope is ambiguous."); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) (concluding that claim terms take on their ordinary and accustomed meanings unless the patentee demonstrates an intent to deviate from that meaning "by characterizing the invention in the intrinsic record using *words or expressions* of manifest exclusion or restriction, representing a clear disavowal of claim scope" (emphasis added)); *VirnetX Inc. v. Apple Inc.*, 931 F.3d 1363, 1379 (Fed. Cir. 2019) (same); *York*, 99 F.3d at 1575 (finding that "the mere invocation" of a prior art reference could not alter the claim term's plain meaning where the file history failed to disclose that the applicants took any steps to actually distinguish the prior art reference).

'280 application); JA-438 (demonstrating that the preliminary amendment was made on July 10, 2009 for the '954 application); JA-1272 (same for the '280 application).

MedComp makes a similar prosecution disclaimer argument with respect to the '639 patent. According to MedComp, Bard amended the claims of the parent patent application, Application No. 11/380,124, to include the limitation "body defining a cavity," and thus "necessar[ily] surrender[ed]" the "meaning (and patent scope)" such that "'body defining a cavity' in the '639 patent must be construed to mean 'the component of the port that delineates the cavity' as MedComp proposes." Dkt. No. 401 at 18–19 (citing JA-879–81). The court rejects MedComp's arguments with regard to the '639 patent for essentially the reasons just discussed. The amendment was not made in response to a rejection by the Examiner, and the prosecution history fails disclose any reason for the amendment. *See* JA-877–84. And as explained, "prosecution history may not be used to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage, such as an amendment to overcome a rejection." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1327 (Fed. Cir. 2003).

Because there is no evidence of prosecution disclaimer, the phrase "body defining a cavity" will be given the meaning that is evident from the context of the intrinsic record for both patent families. The court agrees with Bard that given how the term "body" is used in the specifications and at least some of claims, the "body" can neither be the sole structure that defines the cavity nor limited to components that serve that function. To the contrary, the body indisputably includes components that do not demarcate the cavity (*e.g.*, the cap) and other parts of the port that are not the body also define the boundaries of the cavity (*e.g.*, the septum). The court accordingly construes "body defining a cavity" as follows: "'body' means the structural component(s) of the port; 'defining a cavity' means marking the boundaries of a cavity."

5) "identifier"/"message"

The terms "identifier" and "message" appear in the '723 patent, the '663 patent, the '052 patent, and the '186 patent (collectively, the "Port ID patents"). Although the Port ID patents are all titled "Access Port Identification Systems and Methods," none of the patents actually include any method of identification in the claims themselves. The '723 patent claims only "access port[s] for providing subcutaneous access to a patient." JA-101–02. The'663 patent and '052 patent similarly claim only "power injectable access port[s]." JA-149–50; JA-197–98. And the '186 patent claims "power injectable port assembl[ies]" and "power injectable port system[s]." JA-251–52. The Port ID patent thus claims ports, systems, or assemblies that include an "identifier" or "message" that is "observable via imaging technology subsequent to implantation of the access port" and that "identif[ies] the access port as power injectable." *E.g.*, JA-101 at 12:62–64; JA-150 at 13:1–4; JA-197 at 12:62–64;; JA-251 at 13:46–49.

The term "message" appears in claims 1, 7, and 8 of the '723 patent, each of which requires an access port to have a "bottom surface further including at least one alphanumeric message observable via imaging technology subsequent to implantation of the access port, the alphanumeric message identifying the access port as being power injectable." JA-101 at 12:61–65. And the term "identifier" appears in the '663 patent, the '052 patent, and the '186 patent, which require a power injectable access port or a power injectable port assembly to include "an identifier observable via imaging technology subsequent to implantation of the access port, the identifier identifying the access port as a power injectable port." JA-150 at 13:1–4; JA-197 at 12:62–64; JA-251 at 13:46–49.

MedComp argues that the printed matter doctrine requires that the terms "identifier" and "message" be construed to mean "a feature of the port that is not printed matter." Dkt. No. 405 at

27–28. Bard maintains that these terms do not trigger the printed matter doctrine and should be given their plain and ordinary meanings. *See* Dkt. No. 506 at 8.

For the following reasons, and applying recently decided Federal Circuit precedent, the court concludes that the printed matter doctrine applies to these disputed terms. It follows that they are not entitled to any patentable weight.

As a threshold matter, when the printed matter doctrine inquiry "only require[s] analyzing and interpreting the meaning of the claim terms," it is "a legal inquiry" that may be properly addressed during claim construction. *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Products IP Ltd.*, 890 F.3d 1024, 1033 (Fed. Cir. 2018) (citing *Markman*, 517 U.S. at 372). But although the printed matter doctrine may be properly addressed during claim construction, MedComp has not cited, and the court is not aware of, any case where a court used the doctrine at the claim construction stage to limit the scope of the claims so as to exclude printed matter. To the contrary, it appears that the doctrine has no effect on how the court construes claim terms: rather, at the claim construction stage, the court decides only whether the doctrine applies to the terms or phrases at issue.[6]

[6] It appears that the printed matter doctrine is typically addressed during the claim construction in connection with novelty or obviousness challenges. "While the doctrine's underlying rationale is in subject matter eligibility, its application has been in analyzing other patentability requirements, including novelty under 35 U.S.C. § 102, *e.g.*, *King*, 616 F.3d at 1279, and nonobviousness under 35 U.S.C. § 103, *e.g.*, *In re Huai-Hung Kao*, 639 F.3d 1057, 1072–74 (Fed. Cir. 2011)." *Praxair*, 890 F.3d at 1032. Thus, "many of [the Federal Circuit's] printed matter cases have arisen in the context of anticipation or obviousness." *Id.* at 1033. Although MedComp does not raise an obviousness or novelty challenge in its motion for partial summary judgment, it does raise a patent eligibility challenge under 35 U.S.C. § 101. *See* Dkt. No. 402 at 8–9. The court does not rule on this challenge at this time; rather, it addresses only whether the printed matter doctrine applies to the disputed terms.

In *Praxair*, for example, the Federal Circuit reviewed and upheld the Patent Trial and Appeal Board's claim construction of certain claim terms as well as its application of the printed matter doctrine, because "it underlies the ultimate obviousness issue." *Id.* at 1031. But when determining there the printed matter doctrine applied to one of the claim terms at issue, the Patent Trial and Appeal Board did not actually give that term a specific construction—unlike the other claim terms to which the printed matter doctrine did not apply and to which it gave specific constructions. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Products IP Ltd.*, IPR2015-00529, 2016 WL 3648375, at *6–12 (Patent Tr. & App. Bd. July 7, 2016). In its construction of the term to which the printed matter doctrine applied, the Board simply held that the term claimed printed matter that lacked a functional relationship to the substrate and thus was not entitled to patentable weight. *See id.* at *7–9; *see also, e.g.*, *In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015) (noting that when determining a claim's patentability and performing a printed matter doctrine analysis, the court "[does] not strike out the printed matter and analyze a 'new' claim, but simply [does] not give the printed matter any patentable weight: it may not be a basis for distinguishing prior art").

The printed matter doctrine applies "if a [patent] limitation claims (a) printed matter that (b) is not functionally or structurally related to the physical substrate holding the printed matter." *In re Distefano*, 808 F.3d at 848. The court thus must first determine whether a disputed limitation claims printed matter. If it does, the court then determines whether the printed matter has a functional or structural relation to the substrate—usually, but not always the physical object on which the matter is printed. *See id.* at 850; *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010). If either step is not satisfied, then the printed matter doctrine does not apply. If the printed matter doctrine does apply, the printed matter "does not lend any

patentable weight to the patentability analysis." *In re Distefano*, 808 F.3d at 848. For the following reasons, the court finds that "identifier" and "message" are directed to printed matter, and that there is no functional relationship between the claimed printed matter and the substrate. It follows that the printed matter doctrine applies.

a) "Identifier" and "message" are directed to printed matter

A claim limitation is directed to printed matter if it is "directed to the content of information." *Praxair*, 890 F.3d at 1032. The specific "content" need not literally be "printed" material and may take many different forms. *See id.* (finding that claim limitations directed to mental steps that attempt to capture the content of information are directed to printed matter); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (holding that a claimed step of informing someone about an inherent property of a method was directed to printed matter). By contrast, a claim limitation is not directed to printed matter when it is indifferent to the content of information. *See In Re Distefano*, 808 F.3d at 851 (holding that the relevant limitation was not printed matter because although selected web assets can and likely do communicate some information, the content of the information is not claimed); *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (holding that printed matter doctrine did not apply to sequences of bits stored in memory because the claims dictated how application programs manage information, not the information content of the memory).

Bard argues that the claim limitations at issue here dictate only *how* an "identifier" or "message" conveys information—by an x-ray or other imaging device—but not the *content* of the information conveyed. *See* Dkt. No. 506 at 17–18. Bard thus argues that these limitations are "indifferent to what exactly the message is as opposed to how it can be observed" and that "an identifier is neutral as to content as long as it is viewable once implanted." Dkt. No. 511 at 6.

But this cannot be correct. By its own admission, Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging, *see* Dkt. No. 515 at 4, and it does not claim any imaging technology or the generic use of radiopaque markings for conveying any and all types of messages. Rather, as Bard admitted in its brief, "Bard's ID patents define the function that the 'identifier' and 'message' must perform." Dkt. No. 511 at 6. To take one typical example: the '663 patent requires "an identifier observable via imaging technology subsequent to implantation" that "identif[ies] the access port as a power injectable port." JA-150 at 13:1–4. The Port ID patents thus require radiopaque "identifiers" and "messages" that convey to medical professionals that particular ports may be safely used for power injection.

To be sure, the claim limitations do not require specific words, such as "CT," *see* Dkt. No. 506 at 17, nor do they dictate the precise form the content conveyed by the "identifier" or "message" must take. But the claim limitations containing these terms are not, and cannot be, indifferent to content. If they were—if, for example, they encompassed radiopaque markings conveying nothing more than the date the port was implanted, the patient's birthday, or, more fancifully, a greeting or pithy aphorism—that would entirely defeat the purpose of the claimed inventions. It is thus clear that regardless of the specific wording or symbols used, the "identifier" or "message" must indicate that a port is power injectable. It follows that the "identifier" and "message" limitations are directed to the content of information.

b) "Identifier" and "message" do not have a functional relation to the substrate.

A court's finding that a claim limitation is directed toward printed matter does not end the inquiry. The court must next consider whether the claimed printed matter "is functionally or structurally related to the associated physical substrate." *In re Distefano*, 808 F.3d at 851.

"Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983).

In this case, the Port ID patents claim power injectable access ports as well as systems and assemblies for identifying power injectable access ports. *See* JA-101–02; JA-149–50; JA-197–98; JA-251–52. The inquiry here is thus whether the printed matter limitations—the required "identifiers" or "messages"—have a "functional relationship" with the claimed access ports, assemblies, or systems. The court believes that a recent Federal Circuit decision compels the conclusion that they do not.

In *Bard v. AngioDynamics*, the Federal Circuit analyzed whether the printed matter doctrine applied to the claims in three of Bard's patents, U.S. Patent Nos. 8,475,417 and 8,545,460, which claimed "'assemblies' and 'systems' for identifying a vascular access port as suitable for power injection," as well as US. Patent No. 8,805,478, which claimed "methods for performing a power injection procedure." *C R Bard Inc. v. AngioDynamics, Inc.*, 2020 WL 6573331, at *2 (Fed. Cir. Nov. 10, 2020). The claims asserted in that case required one or more markers "identifying" or "confirming" that an implanted access port is suitable for power injection. *Id.* at *7. The Federal Circuit held that "the asserted claims contain printed matter that is not functionally related to the remaining elements of the claims." *Id.* at *6. The court rejected the argument that "information conveyed by the markers provides new functionality to the port because it makes the port 'self-identifying.'" *Id.* at *7. As the court explained, "[a] conclusion that mere identification of a device's own functionality is sufficient to constitute new functionality for purposes of the printed matter doctrine would eviscerate our established case law that 'simply adding new instructions to a known product' does not create a functional

relationship." *Id*. (citations omitted). The court also rejected the argument that the printed matter is "functionally related to the power injection step of the method claims because the medical provider performs the power injection 'based on' the identification of the port's functionality." *Id.* The court held that "there is no language in the claims suggesting such a causal relationship" and that there is "no persuasive basis for reading that limitation into the claims." *Id.*

Although there are some differences between the patents analyzed in *AngioDynamics* and the Port ID patents, the court concludes that the portions and characteristics of those patents' limitations on which the Federal Circuit's analysis turned are materially indistinguishable from the relevant portions and characteristics of the limitations at issue here. It follows that the Federal Circuit's holding in *AngioDynamics* controls here as well.[7] Because the limitations requiring an "identifier" or "message" are directed to the content of information and do not have a functional relationship to the claimed ports, systems, and assemblies, the court finds that the printed matter doctrine applies and that these terms are not entitled to any patentable weight.

DATED this 24th day of November, 2020.

BY THE COURT:

Howard C. Nielson, Jr.
United States District Judge

[7] To be sure, the Federal Circuit also stated that "each claim as a whole is patent eligible because none are solely directed to the printed matter." *AngioDynamics*, 2020 WL 6573331 at *6. As noted, *see supra* n.6, the court does not address patent eligibility at this time. In addition, in *AngioDynamics*, the "the parties agree[d] that the asserted claims include[d] printed matter." *Id.* at *7. Here that is disputed but, as discussed above, the court concludes that the limitations involving messages or identifiers are directed to the content of information. *See supra* at (III)(B)(5)(a).